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## A Road to Unification: Patent Litigation in the United Kingdom 1990-2012

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# A Road to Unification: Patent Litigation in the United Kingdom 1990–2012

Justin Watts\* and Tom Alkin\*\*

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## INTRODUCTION

Landmark moments in patent law are rare. Henry VI can claim the earliest of them in 1449 by granting letters patent for a new method of making stained glass.<sup>1</sup> Parliament stepped in nearly 200 years later, in 1624, when the Statute of Monopolies rendered all monopolies illegal save for those granted for a term of fourteen years for “working or making of any manner of new manufactures within this Realm to the true and first inventor” (a principle that

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<sup>1</sup> See *History of Patents*, INTELLECTUAL PROPERTY OFFICE, <http://www.ipo.gov.uk/p-history.htm> (last visited Sept. 21, 2012).

remains in place to this day).<sup>2</sup> Patents then were still granted by royal prerogative and bore a royal command that was the basis for adjudicating infringement. Parliament did not turn its attention to infringement until the 1970s, when the United Kingdom joined the European Common Market and the European Patents Convention (the “EPC”), finally giving the UK system a wholly statutory basis.<sup>3</sup>

The EPC’s primary purpose was to harmonize the principles of patentability among the contracting states.<sup>4</sup> A secondary purpose was to create a central European Patent Office (the “EPO”).<sup>5</sup> The EPO would have the power to grant patents that would be enforceable in their national territories—without any reference to the national office and, uniquely, without the supervision of any state court.<sup>6</sup> To this extent, the EPC created a truly supranational patent system.

The UK implemented the EPC through the Patents Act 1977 (the “1977 Act”).<sup>7</sup> The 1977 Act describes itself in its preamble as “a new law of patents.”<sup>8</sup> Patent attorneys were immediately coming to terms with the EPC in their dealings with Munich. But domestically, the UK courts and those acting before them carried on as if nothing material had changed, looking to the words of the 1977 Act and paying little regard to the underlying EPC. For the next decade they tended to turn to pre-1977 case law as an aid to interpretation, in preference to the developing case law of any other EPC member states or the EPO. There were four related reasons for this. First, patents granted under the new Act took time to find their way into the courts. Secondly, the senior patent

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<sup>2</sup> Statute of Monopolies, 1624, 21 Jac., c. 3, § 6 (Eng.); see also *History of Patents in the Tudors and Stuarts Period*, INTELLECTUAL PROPERTY OFFICE, <http://www.ipo.gov.uk/types/patent/p-about/p-what/p-history/p-history-tudor.htm> (last visited Sept. 21, 2012).

<sup>3</sup> See *History of Patents in the Twentieth Century*, INTELLECTUAL PROPERTY OFFICE, <http://www.ipo.gov.uk/types/patent/p-about/p-what/p-history/p-history-20century.htm> (last visited Sept. 21, 2012).

<sup>4</sup> See Convention on the Grant of European Patents (European Patent Convention), art. 1, Oct. 5, 1973, 1065 U.N.T.S. 255 [hereinafter EPC].

<sup>5</sup> *Id.* art. 4, 1065 U.N.T.S. at 259.

<sup>6</sup> See *id.* art. 2, 1065 U.N.T.S. at 259.

<sup>7</sup> Patents Act, 1977, c. 37 (U.K.).

<sup>8</sup> *Id.*

lawyers of the day—the partners, QCs and judges—had all grown up under the old law. Thirdly, much of the old law remained in force for patents granted before the new Act came into force. Fourthly, judges were simply not as used to European influence as they are today.

In 1991 the status quo began to change as the first in a series of important patent cases under the 1977 Act came before the UK's highest court, the House of Lords. In each, the court had to grapple with the fundamental policy question at the heart of any difficult patent case: did the patentee's contribution to public knowledge justify the monopoly it was claiming? For over 500 years the English courts had been used to resolving these questions independently. In 1991 it became apparent they were no longer at liberty to do so. Their duty was to interpret a new law of patents which applied not only in the UK but throughout the continent. While it was not yet certain what this new law meant, it was clear that the contracting states intended that its application be uniform. But, unable to supervise one another, how were the national courts to achieve this uniformity? The practical answer, decided the House of Lords, was the EPO.

The Supreme Court of the United Kingdom (formerly the House of Lords) chooses the cases it will hear, and only hears cases raising a point of law of general public importance.<sup>9</sup> It has heard only a handful of cases over the last twenty years. But those cases are the most important precedent in UK law and, with increasing clarity and insistence, as will be seen, they directed the lower courts to treat the EPO as the *de facto* final arbiter of the UK's law of patents. Whether this development was intended or even foreseen by the founding fathers of the EPC is unclear. But with hindsight, it was probably inevitable.

The role of practitioners has reflected (and perhaps even led) the internationalization of substantive law recognized in House of

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<sup>9</sup> The test is set out in paragraph 3.3.3 of the UK Supreme Court Practice direction 3: “an arguable point of law of general public importance which ought to be considered by the Supreme Court at that time, bearing in mind that the matter will already have been the subject of judicial decision and may have already been reviewed on appeal.” Practice Direction (Applications for Permissions to Appeal) (Supreme Court), [2012], para. 3.3.3, available at <http://www.supremecourt.gov.uk/docs/practice-direction-03.pdf>.

Lords decisions. The chinks in UK defences to mainland European and EPO case law that first showed up in the early 1990s have gradually been opened. This process will continue inexorably, and with renewed vigour, as the final steps are taken to implementing the new European patent “package”—the Unitary Patent and Unified Patents Court.

This paper uses seven key Supreme Court/House of Lords decisions to examine the growing influence of the EPO.<sup>10</sup> It then considers how the new European patents package will fit into the delicate balance that has been achieved between national courts and the EPO, and its likely effect on the development of Europe’s law of patents. Finally, it looks at the way in which practice for litigators has changed over the last two decades and what the coming decades may hold.

#### I. 1991—*ASAHI*’S APPLICATION<sup>11</sup>

The essential issue in *Asahi* was whether a patentee is entitled to a patent when his invention already forms part of the state of the art, but is not yet enabled.<sup>12</sup>

In February 1985, Dainippon Pharmaceutical Company Limited applied for a European Patent claiming human tumour necrosis factor (or “HTNF”) (“Dainippon 2”).<sup>13</sup> Dainippon 2 claimed priority from a Japanese application filed in March 1984 (“Dainippon 1”).<sup>14</sup> In April 1985, Asahi filed an application for a UK patent claiming HTNF (“Asahi 2”).<sup>15</sup> Asahi 2 claimed priority from a U.S. application filed in April 1984 (“Asahi 1”).<sup>16</sup> It was common ground that Dainippon 1 disclosed no way of actually making HTNF, only its sequence, while the other three applications did disclose a way of making HTNF.<sup>17</sup>

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<sup>10</sup> In this paper we refer to the EPO as a convenient general shorthand, but more particularly we also refer to the decisions of the Boards of Appeal of the EPO.

<sup>11</sup> *Asahi Kasei Kogyo KK’s Application*, [1991] R.P.C. 485 (H.L.).

<sup>12</sup> *Id.*

<sup>13</sup> *Id.* at 505.

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> *Id.* at 500, 531.

The examiner rejected Asahi 2 on the grounds that it lacked novelty over Dainippon 2, which was in turn entitled to priority from Dainippon 1.<sup>18</sup> On appeal, the issue resolved into twin questions: (i) whether, for Dainippon 1 to confer priority on Dainippon 2, it was necessary for Dainippon 1 to constitute not merely a disclosure but an *enabling* disclosure of HTNF; and (ii) whether, to destroy the novelty of (or ‘anticipate’) Asahi 2, Dainippon 2 also had to constitute not merely a disclosure but an *enabling* disclosure of HTNF.<sup>19</sup>

The old English law on the point was unclear. In *ICI/Pyridine Herbicides*, however, the EPO had decided that (1) a claim to a chemical formula was not anticipated by the disclosure of that formula in the prior art unless that disclosure was also enabling and that (2) the test for whether a prior art disclosure was enabling was the same as the test for sufficiency.<sup>20</sup> In *Collaborative Research Inc/Preprorennin*, the EPO held that the same test had to be satisfied for the purpose of claiming priority, i.e. the priority document had to be not merely a disclosure of the invention but an enabling disclosure.<sup>21</sup>

In these cases the EPO had (standing back from the language of the EPC) recognized that, if a claimed invention could be anticipated by a mere disclosure which enabled nothing, there was a risk that genuine contributions to public knowledge in the form of enabling disclosures would not be rewarded.<sup>22</sup> It followed inexorably that, if a non-enabling disclosure should not itself be novelty-destroying, the same disclosure should not be indirectly novelty-destroying through the priority system.

The UK Patent Office, the Patents Court and the Court of Appeal all rejected the EPO’s logic and decided the case against Asahi on either old case law or by narrowly construing the 1977 Act.<sup>23</sup> When the case reached the House of Lords, Lord Oliver

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<sup>18</sup> *Id.* at 531.

<sup>19</sup> *See id.* at 535.

<sup>20</sup> *Id.* at 551 (citing Case T-206/83, *ICI/Pyridine Herbicides*, 1987 O.J. E.P.O. 5).

<sup>21</sup> *Id.* at 512 (citing Case T-81/87, *Collaborative Research/Preprorennin*, 1990 O.J. E.P.O. 250).

<sup>22</sup> *See, e.g., id.* at 513.

<sup>23</sup> *See id.* at 486.

(who gave the leading speech) took a very different approach. He accepted Asahi's argument, holding that UK law had arrived independently at the conclusion that an enabling disclosure was required for anticipation, and therefore priority, observing:

It should be added that the same approach as that adopted by Falconer J. in the *Genentech* case has been adopted in the [Pyrimidines and Preprorennin cases] . . . . These decisions, as was pointed out by Dillon L.J. in the instant case, are not binding in the United Kingdom, but they must carry considerable persuasive authority having regard to the provisions of section 130(7) [which declares certain sections of the 1977 Act to have same effect as equivalent provisions of the EPC] and the desirability of avoiding, so far as possible, divergent jurisprudence on the interpretation of broadly parallel provisions.<sup>24</sup>

Asahi had been the first to teach the world how to obtain HTNF.<sup>25</sup> It followed that it was entitled to a patent for this contribution.<sup>26</sup> The anticipated objection based on *Dainippon 1* failed.

It is hard to fault the EPO's reasoning in the *Pyrimidines* and *Preprorennin* cases and it may therefore be unsurprising that Lord Oliver agreed with it. But a precedent had now been set: although EPO decisions were not binding on the UK courts, the courts were nevertheless to treat those decisions as carrying "considerable persuasive authority."<sup>27</sup>

## II. 1996—*MERRELL DOW V. NORTON*<sup>28</sup>

In *Merrell Dow* the essential issue was how much detail about an invention a patentee needed to disclose to be entitled to a patent.<sup>29</sup>

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<sup>24</sup> *Id.* at 540.

<sup>25</sup> *See id.* at 500.

<sup>26</sup> *See id.* at 542.

<sup>27</sup> *Id.* at 540.

<sup>28</sup> *Merrell Dow Pharmaceuticals, Inc. v. Norton & Co. Ltd.*, [1996] R.P.C. 76 (H.L.).

In 1972, Merrell Dow obtained a patent for an antihistamine called terfenadine.<sup>30</sup> Having patented terfenadine, it discovered that the active agent was in fact an acid metabolite of terfenadine formed in the liver.<sup>31</sup> In 1980, Merrell Dow obtained a patent for the acid metabolite.<sup>32</sup> When the terfenadine patent expired in 1992, Merrell Dow claimed it could continue to prevent competitors selling terfenadine because to do so would be to knowingly provide a “means essential” for producing the acid metabolite.<sup>33</sup> The question that came before the House of Lords was whether the claim to the acid metabolite was anticipated by either the original terfenadine specification (“anticipation by disclosure”) or the administration of terfenadine to volunteers in the clinical trials (“anticipation by use”).<sup>34</sup>

Lord Hoffmann gave the leading judgment. He started by noting that the 1977 Act requires section 2, which deals with anticipation, to be given the same effect as the corresponding provision of the EPC, and observed:

It is therefore the duty of the United Kingdom courts to construe section 2 so that, so far as possible, it has the same effect as Article 54. For this purpose, it must have regard to the decisions of the European Patent Office (“EPO”) on the construction of the EPC. These decisions are not strictly binding upon courts in the United Kingdom but they are of *great persuasive authority*; first, because they are decisions of expert courts (the Boards of Appeal and Enlarged Board of Appeal of the EPO) involved daily in the administration of the EPC and secondly, because *it would be highly undesirable for the provisions of the EPC to be construed differently in the EPO from the way they*

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<sup>29</sup> *Id.*

<sup>30</sup> *Id.* at 80.

<sup>31</sup> *See id.*

<sup>32</sup> *Id.*

<sup>33</sup> *See id.* at 81.

<sup>34</sup> *See id.* at 82–84.



*are interpreted in the national courts of a Contracting State.*<sup>35</sup>

Lord Hoffmann's first contribution in the House of Lords to the UK's law of patents was therefore to emphasize the EPO's authority in construing the EPC and, by extension, the 1977 Act. His reasoning was quite explicit, as the emphasised passage demonstrates. Consistency was the paramount concern.<sup>36</sup>

Lord Hoffmann dealt with the "anticipation by use" argument first.<sup>37</sup> Under the old law, there was no question that the administration of terfenadine to volunteers in the clinical trials, with the inevitable consequence of producing the acid metabolite in their livers, would have anticipated the acid metabolite patent.<sup>38</sup> It was clear that the acid metabolite had been produced before the priority of the patent,<sup>39</sup> whether anyone was aware of this or not, and this would have been enough to make it part of the state of the art.<sup>40</sup> It was argued that the new law was no different.<sup>41</sup>

Lord Hoffmann disagreed:

I think that this argument . . . dissolves completely when one looks, as one must, at Article 54 [the definition of novelty in the EPC]. This provision makes it clear that to be part of the state of the art, *the invention* must have been made available to the public. *An invention is a piece of information.* Making matter available to the public within the meaning of section 2(2) therefore requires the communication of information. The use of a product makes the invention part of the state of the art only so far as that use makes available the necessary information.<sup>42</sup>

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<sup>35</sup> *Id.* at 82 (emphasis added).

<sup>36</sup> *See id.*

<sup>37</sup> *See id.* at 85.

<sup>38</sup> *See id.*

<sup>39</sup> *See id.* at 80.

<sup>40</sup> *See id.* at 85.

<sup>41</sup> *See id.* at 86.

<sup>42</sup> *Id.* (second emphasis added). It may also be observed that, having characterized an invention as "a piece of information," it is hard to see how the "anticipation by use"

In other words, whereas under the old law “uninformative use” could anticipate a patent, under the new law it could not.

Next he turned to the “anticipation by disclosure” argument. It was not suggested that the terfenadine patent made any specific reference to the acid metabolite.<sup>43</sup> All that was known at the time was that terfenadine created some kind of chemical reaction in the human body, which produced an antihistamine effect. To this effect, the terfenadine specification contained the line: “a part of the chemical reaction in the human body produced by the ingestion of terfenadine and having an anti-histamine effect.”<sup>44</sup>

It was argued that for all practical purposes this was an enabling disclosure of the acid metabolite.<sup>45</sup> It was a description of the essential characteristic of the metabolite, namely its anti-histamine effect, and of how to make it and therefore the fact that its precise chemical composition was not described was immaterial.<sup>46</sup> Merrell Dow countered that only disclosure of a product by its chemical composition sufficed under the new law to make a product part of the state of the art.<sup>47</sup>

Lord Hoffmann turned to EPO case law. He noted that, in *Bayer/Diastereomers*, the EPO held that disclosure of a product described as the product of a specified process makes the product itself part of the state of the art whether or not its composition was also disclosed.<sup>48</sup> It followed, he reasoned, that the disclosure of the chemical composition of a product is plainly not required to make a product part of the state of the art.<sup>49</sup> Lord Hoffmann then went on to consider from first principles how much information about a product was required to make it part of the state of the art.<sup>50</sup> He

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could have amounted to an enabling disclosure when the volunteers were not furnished with adequate information (i.e. the fact that they were taking terfenadine) to go away and continue to work the invention at will.

<sup>43</sup> *Id.* at 87.

<sup>44</sup> *Id.* at 90.

<sup>45</sup> *See id.* at 88–89.

<sup>46</sup> *See id.* at 86.

<sup>47</sup> *See id.* at 89.

<sup>48</sup> *Id.* at 89 (citing Case T-12/81, *Diastereomers*, 1982 O.J. E.P.O. 296). This is a so-called “product by process claim,” a theme to which we shall return.

<sup>49</sup> *See id.* at 89–90.

<sup>50</sup> *See id.* at 89.

concluded that an invention forms “part of the state of the art if the information which has been disclosed enables the public to know the product under a description sufficient to work the invention.”<sup>51</sup> The terfenadine patent enabled the public to know the acid metabolite as part of the chemical reaction produced by ingesting terfenadine.<sup>52</sup> This was enough. He pithily summed up his reasoning by observing that, in much the same way, quinine had been part of the state of the art long before its chemical composition was discovered by western scientists.<sup>53</sup>

At its core, Merrell Dow’s argument was that it deserved its extended monopoly because it had revealed that terfenadine worked because of the acid metabolite.<sup>54</sup> Merrell Dow acknowledged a striking consequence of this argument: if a competitor had discovered the acid metabolite and patented it, that competitor would have been entitled to prevent Merrell Dow selling terfenadine.<sup>55</sup> Instinctively, one feels this cannot be correct. But why not? The answer is simple. Merrell Dow had already taught the public that taking terfenadine produced an antihistamine effect. The further discovery that this effect is actually produced by the acid metabolite, while of academic interest, gave the public no additional relevant knowledge.<sup>56</sup>

The fundamental question was therefore how much information about an invention is sufficient to make that invention part of the state of the art?<sup>57</sup> The EPO’s approach to product by process claims provided the answer.<sup>58</sup> If the public has sufficient information to obtain a product and know its practical application, that is enough. A patentee need not teach any more than this, and a patentee who does teach more than this is not entitled to a second

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<sup>51</sup> *Id.*

<sup>52</sup> *See id.* at 90.

<sup>53</sup> *Id.* at 91 (“The Amazonian Indian who treats himself with powdered bark for fever is using quinine, even if he thinks the reason why the treatment is effective is that the tree is favoured by the Gods.”).

<sup>54</sup> *See id.* at 80–81.

<sup>55</sup> *See id.*

<sup>56</sup> *See id.*

<sup>57</sup> *See id.* at 84–86.

<sup>58</sup> *Id.* at 87.

patent for the same product. As in *Asahi*, the touchstone was the practical value of the disclosure to the public.<sup>59</sup>

Again, it is hard to fault the EPO's reasoning in *Bayer/Diastereomers*.<sup>60</sup> No doubt this prompted Lord Hoffmann not only to draw on that reasoning, but also to emphasize the persuasive authority of the EPO's decisions, thereby confirming the *Asahi* precedent.

### III. 1997—*BIOGEN V. MEDEVA*<sup>61</sup>

In *Biogen*, the essential question was not whether Biogen was entitled to a monopoly at all, but how broad that monopoly should be.<sup>62</sup>

Biogen, Inc. was set up in 1978 to exploit recombinant DNA technology in the production of useful proteins.<sup>63</sup> One initial target was antigens of the Hepatitis B virus.<sup>64</sup> Professor Sir Kenneth Murray, a molecular biologist and one of Biogen's founders, split the then unsequenced HBV genome into large fragments, spliced these into plasmid loops and introduced this recombinant DNA into bacteria.<sup>65</sup> His hope, but certainly not his expectation, was that one of the fragments would contain a suitable HBV antigen gene and that this would be “expressed” (i.e. translated into HBV antigen protein) by the bacteria.<sup>66</sup>

The state of the art being what it was at the time, there was much reason to doubt that Professor Murray's approach would work, but it did.<sup>67</sup> Biogen immediately filed for patent protection, first in the UK (Biogen 1), and later at the EPO (Biogen 2).<sup>68</sup> Biogen 2, asserting priority from Biogen 1, claimed any

<sup>59</sup> See *id.*; see also *Asahi Kasei Kogyo KK's Application*, [1991] R.P.C. 485 (H.L.).

<sup>60</sup> Case T-12/81, *Diastereomers*, 1982 O.J. EPO 296.

<sup>61</sup> *Biogen v. Medeva*, [1997] R.P.C. 1 (H.L.).

<sup>62</sup> See *id.* at 4.

<sup>63</sup> See *id.* at 33.

<sup>64</sup> See *id.* (stating that these could be used to test for HBV infection and to develop a vaccine).

<sup>65</sup> See *id.* at 36–40.

<sup>66</sup> See *id.* at 39.

<sup>67</sup> See *id.* at 36–39.

<sup>68</sup> *Id.* at 33.

recombinant DNA molecule capable of expressing HBV antigens.<sup>69</sup>

In due course Medeva found an entirely new way of producing a recombinant HBV antigen. Biogen sued. In the House of Lords, as in *Asahi*,<sup>70</sup> the issue resolved into whether Biogen 1 enabled Biogen 2.<sup>71</sup> There was no question that the disclosure of Biogen 1 enabled the skilled addressee to make *a* recombinant DNA molecule capable of expressing the HBV antigen.<sup>72</sup> But equally there was no suggestion that it enabled the skilled person to make *all* such molecules.<sup>73</sup>

At first instance, the Patents Court held that an invention was sufficiently enabled if the skilled man could make one embodiment falling within the claim.<sup>74</sup> Its reasoning was based on its interpretation of the EPO's decision in *Genentech/Polypeptide Expression*.<sup>75</sup>

The Court of Appeal, however, reversed the Patents Court on the question of sufficiency, pointing to the *Exxon/Fuel oils* case.<sup>76</sup> In that case, the EPO had held that an invention must be enabled across the full range of the claim, and whether or not this was so was a question of fact in each case.<sup>77</sup>

The House of Lords agreed with the Court of Appeal.<sup>78</sup> Lord Hoffmann explained that the EPO's decision in *Genentech I* had been misinterpreted by the Patents Court:

[T]he Board in *Genentech I/Polypeptide Expression* was doing no more than apply a principle of patent law which has long been established in the United Kingdom, namely, that the specification must

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<sup>69</sup> *Id.* at 40.

<sup>70</sup> *Asahi Kasei Kogyo KK's Application*, [1991] R.P.C. 485 (H.L.).

<sup>71</sup> *See Biogen*, [1997] R.P.C. at 46.

<sup>72</sup> *See id.* at 48.

<sup>73</sup> *See id.*

<sup>74</sup> *See id.* at 49–50.

<sup>75</sup> *See id.* (citing Case T-292/85, *Genentech/Polypeptide expression*, 1989 O.J. EPO 275).

<sup>76</sup> *See id.* at 53–54 (citing Case T-409/91, *Exxon/Fuel Oils*, [1994] E.P.O.R. 149).

<sup>77</sup> *See Case T-409/91, Exxon/Fuel Oils*, [1994] E.P.O.R. 149, 156.

<sup>78</sup> *See Biogen*, [1997] R.P.C. at 53.

enable the invention to be performed to the full extent of the monopoly claimed. If the invention discloses a principle capable of general application, the claims may be in correspondingly general terms. The patentee need not show that he has proved its application in every individual instance. On the other hand, if the claims include a number of discrete methods or products, the patentee must enable the invention to be performed in respect of each of them.<sup>79</sup>

He went on to consider whether or not Biogen 1 disclosed a principle of general application, which entitled it to the broad monopoly claimed.<sup>80</sup> In a now famous passage, he held that it did not:

I return therefore to consider the technical contribution to the art which Professor Murray made in 1978 and disclosed in Biogen 1. As it seems to me, it consisted in showing that despite the uncertainties which then existed . . . known recombinant techniques could nevertheless be used to make the antigens in a prokaryotic host cell. . . . Does this contribution justify a claim to a monopoly of any recombinant method of making the antigens? In my view it does not. The claimed invention is too broad. Its excessive breadth is due, not to the inability of the teaching to produce all the promised results, but to the fact that the same results could be produced by different means. . . . The metaphor used by one of the witnesses was that before the genome had been sequenced everyone was working in the dark. Professor Murray invented a way of working with the genome in the dark. But he did not switch on the light and once the light was on his method was no longer needed.<sup>81</sup>

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<sup>79</sup> *Id.* at 48.

<sup>80</sup> *Id.* at 51–52.

<sup>81</sup> *Id.*

The fundamental question in *Biogen* was familiar: what contribution had Biogen made to the art and how broad a monopoly should it receive for that contribution? As we have seen, the EPO—contrary to the Patents Court’s view—had held that a broad claim had to be enabled across its full breadth, and that whether that was so was a question of fact in each case.<sup>82</sup> Lord Hoffmann went further by reducing the EPO’s approach to a rule: where the patentee had invented a “principle of general application”—i.e. a principle which could be expected to work in the same way whatever the precise details of the components or reagents used—he was entitled to a broad claim.<sup>83</sup> Lord Hoffman found that Professor Murray had invented no such principle, and so was not entitled to its broad claim.<sup>84</sup>

While *Biogen* showed the House of Lords seeking to follow EPO case law, the consequence turned out to be a divergence between UK and EPO case law. As we will explore below, the House of Lords does not usually revisit the same ground in rapid succession, but the difficulties created by *Biogen* brought the sufficiency issue back before the Supreme Court in 2009.

#### IV. 2005—*KIRIN-AMGEN V. HOECHST MARION ROUSSEL LTD.*<sup>85</sup>

The formal issue in *Kirin-Amgen* was construction.<sup>86</sup> Did Amgen’s claim catch a rival product or did it not? Again, however, the fundamental question was whether Amgen’s contribution to the art entitled it to the broad monopoly claimed.<sup>87</sup>

By 1983, it was well known that the human kidney protein Erythropoietin (“EPO”) was responsible for stimulating the production of red blood cells in bone marrow.<sup>88</sup> EPO’s potential as a treatment for anaemia in patients with kidney disease was widely

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<sup>82</sup> See T-409/91, *Exxon/Fuel Oils*, [1994] E.P.O.R. 149, 156.

<sup>83</sup> See *Biogen*, [1997] R.P.C. at 51.

<sup>84</sup> See *id.*

<sup>85</sup> *Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd.*, [2004] UKHL 46, [2005] R.P.C. 9.

<sup>86</sup> See *id.* at 184–87 [27–45].

<sup>87</sup> See *id.* at 171 [H9].

<sup>88</sup> See *id.* at 180 [8].

recognized. Small amounts of the protein had been painstakingly isolated and purified from human urine, but obtaining enough for therapeutic use by this method was out of the question.<sup>89</sup>

Amgen was the first to sequence the gene for EPO.<sup>90</sup> Equipped with this sequence, it was able to isolate the gene from a human donor cell and introduce it into a Chinese hamster cell in culture (a “CHO cell”), which could then be used to produce large amounts of EPO.<sup>91</sup> Amgen filed a patent application claiming EPO produced by the expression of recombinant DNA in a “host cell.”

A competitor, TKT, discovered a new way of using recombinant DNA to produce EPO. Instead of extracting the gene from a human cell and putting it into an animal cell, TKT used recombinant DNA techniques to modify the EPO gene within a *human* cell in culture so that it expressed large amounts of EPO.<sup>92</sup> TKT called this technique “gene activation” and its product “GA-EPO.”<sup>93</sup> Amgen sued. The key question was whether Amgen’s claim covered GA-EPO even though this had in fact been produced in a modified human cell as opposed to a “host cell.”<sup>94</sup>

Section 125 of the 1977 Patent Act<sup>95</sup> directed the Courts to construe patent claims in accordance with Article 69 of the EPC and the “Protocol on the Interpretation of Article 69” (the “Protocol”). Article 69 provides:

The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.<sup>96</sup>

The Protocol then explains how Article 69 itself should be interpreted:

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<sup>89</sup> *Id.* at 179 [5].

<sup>90</sup> *Id.* at 179–80 [6].

<sup>91</sup> *Id.* at 180 [9].

<sup>92</sup> *Id.* at 180–81 [10].

<sup>93</sup> *Id.*

<sup>94</sup> *See id.* at 179 [2].

<sup>95</sup> The Patents Act, 1977, c. 37, § 125 (Eng.).

<sup>96</sup> EPC, *supra* note 4, art. 69.



Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.<sup>97</sup>

The Protocol represented perhaps the most striking compromise between the signatories to the EPC, particularly the UK and Germany. The UK and Germany were generally taken to represent the extreme ends of construction, with their respective approaches caricatured as a strictly literal approach to claim construction on the one hand and a very loose approach to claim construction on the other.<sup>98</sup> The purpose of the Protocol was to make clear that, under the new law, the courts of the contracting states were to strike a balance between these two extremes.<sup>99</sup>

Following the entry into force of the 1977 Act, the Patents Court decided that the Protocol simply reflected the traditional UK

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<sup>97</sup> European Patent Convention, Protocol on the Interpretation of Article 69, art. 1, Nov. 29, 2000, available at <http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/ma2a.html>.

<sup>98</sup> See, e.g., Thomas K. McBride, Jr., *Patent Practice in London—Local Internationalism: How Patent Law Magnifies the Relationship of the United Kingdom with Europe, the United States, and the Rest of the World*, 2 LOY. U. CHI. INT'L. L. REV. 31, 40–43 (2005).

<sup>99</sup> See *Kirin-Amgen*, [2005] R.P.C. at 183–84 [23–26]; *Auchincloss v. Agricultural and Veterinary Supplies*, [1997] R.P.C. 649, 663.

approach to construing patent claims.<sup>100</sup> As we shall see, this was to prove controversial. Some knowledge of the controversy as it unfolded is necessary to understand *Kirin-Amgen*.

The old approach to claim construction had been settled in *Catnic v. Hill & Smith*.<sup>101</sup> The correct approach, as explained by Lord Diplock, was “purposive construction.”

A patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge. The question in each case is: whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that *any* variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked. . . . [The question] is to be answered in the negative only when it would be apparent to any reader skilled in the art that a particular descriptive word or phrase used in a claim cannot have been intended by a patentee, who was also skilled in the art, to exclude minor variants which, to the knowledge of both him and the readers to whom the patent was addressed, could have no material effect upon the way in which the invention worked.<sup>102</sup>

The *Catnic* approach was applied under the 1977 Act in *Improver Corp. v. Remington Consumer Prods. Ltd.*<sup>103</sup> The case

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<sup>100</sup> See, e.g., *A.C. Edwards Ltd. v. Acme Signs & Displays Ltd.*, [1992] R.P.C. 131, 136; *Southco Inc. v. Dzus Fastener Europe Ltd.*, [1992] R.P.C. 299, 312; *Improver Corp. v. Remington Consumer Prods. Ltd.*, [1990] F.S.R. 181, 190.

<sup>101</sup> *Catnic Components Ltd. v. Hill & Smith Ltd.*, [1982] R.P.C. 183, 242–43 (H.L.).

<sup>102</sup> *Id.*

<sup>103</sup> *Improver*, [1990] F.S.R. 181, 188–90.

concerned a hair removal device called a depilator.<sup>104</sup> The functional part of Improver's patented original device consisted of a rotating, curved spring.<sup>105</sup> Hairs entered into the space between the coils of the spring on the convex side, and were gripped and removed as the rotating coils were pressed together on the concave side.<sup>106</sup> Remington liked the basic idea. It noted that Improver's claim specified the use of a "helical spring" and proceeded to design around the claim, replacing the helical spring with a rotating, curved rubber rod scored with transverse slits.<sup>107</sup> At trial, the key question Judge Hoffmann<sup>108</sup> had to answer was whether, on its true construction, Improver's claim caught Remington's product.<sup>109</sup> He distilled Lord Diplock's guidance on variants in *Catnic* into three questions, the *Improver* or "Protocol" questions, as follows:

- (1) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no—
- (2) Would this (i.e. that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art. If no, the variant is outside the claim. If yes—
- (3) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention. If yes, the variant is outside the claim.<sup>110</sup>

To the first two questions Hoffmann J. answered "no" and "yes" respectively, leaving only the third. As to this, Improver relied strongly on this passage in the specification:

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<sup>104</sup> See *id.* at 184 ("Depilation means the removal of hair by the root, as opposed to shaving which leaves the root behind.").

<sup>105</sup> See *id.* at 184–85.

<sup>106</sup> See *id.*

<sup>107</sup> See *id.* at 187.

<sup>108</sup> Lord Hoffmann was elevated to the Court of Appeal in 1992 and to the House of Lords in 1995.

<sup>109</sup> See *Improver*, [1990] F.S.R. at 188–89.

<sup>110</sup> See *id.* at 189.

It will be evident to those skilled in the art . . . that the present invention may be embodied in other specific forms without departing from the essential attributes thereof . . . and all variations which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.<sup>111</sup>

The specification's language notwithstanding, Judge Hoffmann felt unable to give the term "helical spring" a wide, generic construction and thus held the patent not infringed.<sup>112</sup> Helical spring meant helical spring. He noted that his opinion differed from German courts' result, despite the fact that both English and German courts had purported to apply Article 69 and the Protocol, but at the same time Hoffman J. did not fail to note that he considered the German construction the result of an insufficiently literal approach to construction.<sup>113</sup>

As noted in *PLG v. Ardon*, the German Oberlandesgericht, or higher regional court, retaliated by criticizing Hoffmann J.'s *Improver* opinion for applying a UK pre-1977 approach to construction.<sup>114</sup> The *Ardon* court went on to comment on the inconsistent results:

[It is] unnecessary to consider whether Lord Diplock's purposive construction was an accurate if proleptic application of the Protocol. It clearly went at least part of the way towards the European position by stretching the claims to cover minor variants which obviously have no material effect on the way the invention works. It does not, however, appear to us to be useful to consider whether it went further and may be taken as indicating the proper approach to construction under the Protocol. Such an exercise merely engenders a sterile debate on the precise meaning of Lord Diplock's words, a matter

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<sup>111</sup> *Id.* at 186.

<sup>112</sup> *Id.* at 197.

<sup>113</sup> *See id.* at 197–98.

<sup>114</sup> *See* *PLG Research Ltd. v. Ardon Int'l Ltd.*, [1995] R.P.C. 287, 307–09 (*citing* *Improver Corp. v. Remington Prods. Inc.* [1991] IIC 833 (Ger.)).

which should now be left to legal historians. Lord Diplock was expounding the common law to the construction of a patent. This has been replaced by the approach laid down by the Protocol. If the two approaches are the same, reference to Lord Diplock's formulation is unnecessary, while if they are different it is dangerous. In future, it is to be hoped that attention will be concentrated on the requirements of the Protocol and the developing European jurisprudence and not on those of the common law before 1977.<sup>115</sup>

The Court of Appeal's attempt to consign *Catnic* to legal history was met with rebellion. In *AssiDoman Multipack v. The Mead Corporation*, the specialist Patents Court Judge Aldous retorted:

In that part of their judgment, the Court of Appeal are, I believe, making it clear that their observation on the applicability of "purposive" construction under the 1977 Act are obiter. For myself, I would be loathe to discard 14 years of case law unless it is certain that the "purposive" construction is not the correct approach under the Act. If it be right that "purposive" construction should be left to legal historians, then it is necessary to put forward another means of navigation to enable the court to steer the correct course between Scylla and Charybdis. The middle ground referred to in the Protocol is not clearly defined and every court within the Community has adopted a method of interpretation which it believes to be consistent with the Protocol. . . . There is no European position except that set out in the Protocol.<sup>116</sup>

Then, in *Beloit Technologies Inc. v. Valmet Paper Machinery Inc.* (No. 2), the other senior Patents Court Judge, Jacob J.,

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<sup>115</sup> *Ardon*, [1995] R.P.C. at 309.

<sup>116</sup> *AssiDoman Multipack Ltd. v. Mead Corp.*, [1995] R.P.C. 321, 337.

agreed.<sup>117</sup> When the question came back before the Court of Appeal, the newly elevated Aldous L.J. affirmed his view in *AssiDoman*.<sup>118</sup> “Purposive construction” was to remain the English approach to claims construction, however it was done elsewhere in Europe.

In *Kirin-Amgen*, therefore, *Catnic* remained the law. The judge at first instance had initially reasoned that the skilled person would not understand Amgen’s claim as covering GA-EPO.<sup>119</sup> GA-EPO was not made in a “host cell.” However, that judge then went on to ask the *Improver* questions and decided that the claim did cover GA-EPO after all.<sup>120</sup>

In the House of Lords, Lord Hoffmann reviewed the authorities on construction and confirmed that “purposive construction” was indeed compliant with the Protocol:

The *Catnic* principle of construction is, therefore, in my opinion, precisely in accordance with the Protocol. It is intended to give the patentee the full extent, but not more than the full extent, of the monopoly which a reasonable person skilled in the art, reading the claims in context, would think he was intending to claim.<sup>121</sup>

Turning to the controversy caused by his decision in the *Improver* case, Lord Hoffman observed that ultimately there was only one “compulsory” question: what would the skilled person, reading the claims in context, think the patentee was intending to claim?<sup>122</sup> Sometimes the *Improver* questions would help, sometimes they would not. But they were certainly not mandatory in all cases involving allegedly immaterial variants.<sup>123</sup> Lord Hoffman held that the judge’s initial construction of the claim was correct and that he had simply confused matters by attempting to

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<sup>117</sup> *Beloit Techs. Inc. v. Valmet Paper Mach. Inc.*, [1995] R.P.C. 705, 719–21.

<sup>118</sup> *See Kaster v. Rizla Ltd.*, [1995] R.P.C. 585, 594 (“I have not been persuaded . . . that the views I expressed in *Assi[D]oman* were wrong.”).

<sup>119</sup> *See Kirin-Amgen*, [2005] R.P.C. at 192 [58].

<sup>120</sup> *See id.* at 193–95 [63–75].

<sup>121</sup> *Id.* at 189 [48].

<sup>122</sup> *Id.* at 194 [69].

<sup>123</sup> *See id.*

apply the Protocol questions as well.<sup>124</sup> There is a hint of compromise in the judgment. Purposive construction was the correct approach, but any attempt to define it further was liable to lead to difficulties. Lord Hoffman used the opportunity to further align the approach between European Courts, stating that:

German judges do not ask whether a variant “works in the same way” but whether it solves the problem underlying the invention by means which have the same technical effect. That may be a better way of putting the question because it avoids the ambiguity illustrated by *American Home Products Corporation v Novartis Pharmaceuticals UK Ltd* [2001] RPC 8 over whether “works in the same way” involves an assumption that it works at all.<sup>125</sup>

Lord Hoffmann also held the various claims at issue bad either for lack of novelty or for claims breadth insufficiency. In his judgment’s final passage he observed:

Standing back from the detail, it is clear that Amgen have got themselves into difficulties because, having invented a perfectly good and ground-breaking process for making EPO and its analogues, they were determined to try to patent the protein itself, notwithstanding that, even when isolated, it was not new.<sup>126</sup>

Elsewhere in the judgment, when addressing novelty, Lord Hoffmann emphasized again the increasingly recognized supremacy of EPO case law, and indeed he based his decision on that principle:

I think it is important that the United Kingdom should apply the same law as the EPO and the other Member States when deciding what counts as new for the purposes of the EPC. It is true that this means a change in a practice which has existed for many years. But the difference is unlikely to be of

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<sup>124</sup> *See id.*

<sup>125</sup> *Id.* at 195 [75].

<sup>126</sup> *Id.* at 206 [132].

great practical importance because a patentee can rely instead on the process claim and art. 64(2). It would be most unfortunate if we were to uphold the validity of a patent which would on identical facts have been revoked in opposition proceedings in the EPO. I would therefore allow this part of the appeal.<sup>127</sup>

Again, the fundamental problem was that Amgen had tried to claim more than was justified by their contribution to public knowledge. And again, the House of Lords took the opportunity to emphasize the importance of alignment between European Courts and the supremacy of EPO case law.

V. 2008—*CONOR MEDSYSTEMS V. ANGIOTECH PHARMACEUTICALS*<sup>128</sup>

At issue in *Angiotech* was what exactly the patentee had established at the time of filing about the usefulness and obviousness of its claimed invention.<sup>129</sup> The courts at first instance had found that the patentee had in fact disclosed something useful, but without an investigative basis for that disclosure.<sup>130</sup>

By the early 1990s, the value of stents for treating constricted arteries was well known. However, the presence of a stent often prompted an exaggerated healing response, causing the artery to become constricted again.<sup>131</sup> This process was known as “restenosis.”<sup>132</sup> In 1993, a group of Dutch scientists published a two-part article<sup>133</sup> that reviewed the research that had been done on restenosis, and the two prevailing theories for how it might

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<sup>127</sup> *Id.* at 200 [101] (citation omitted).

<sup>128</sup> *Conor Medsystems Inc. v. Angiotech Pharm. Inc.*, [2008] UKHL 49, [2008] R.P.C. 28.

<sup>129</sup> *Angiotech*, [2008] R.P.C. at 722–23.

<sup>130</sup> *See id.* at 725–26.

<sup>131</sup> *See id.* at 721.

<sup>132</sup> *Id.*

<sup>133</sup> *Id.* (citing Jean-Paul R. Herrman et al., *Pharmacological Approaches to the Prevention of Restenosis Following Angioplasty: The Search for the Holy Grail? (Part I)*, 46 DRUGS 18 (1993); Jean-Paul R. Herrman et al., *Pharmacological Approaches to the Prevention of Restenosis Following Angioplasty: The Search for the Holy Grail? (Part II)*, 46 DRUGS 249 (1993)).



eventually be tackled.<sup>134</sup> The first theory likened the phenomenon to cancer and suggested the use of anti-proliferatives.<sup>135</sup> The second likened the process to clotting, and suggested the use of anti-thromobotics.<sup>136</sup> In a summary dealing with future possibilities, the authors said:

[D]espite 15 years of clinical experience and research in the field of restenosis prevention, this has not yet resulted in the revelation of unequivocal beneficial effects of any particular drug. . . . Whether there is a feasible monotherapy, whether we have to focus on a drug combination, or whether we are only searching for the “Holy Grail” remains to be answered.<sup>137</sup>

In short, then, in 1993, nobody knew precisely how to solve the problem of restenosis—although there was no shortage of ideas.

Back in 1991, however, it had occurred to a medical student called William Hunter that one way of dealing with restenosis might be to seek to inhibit the growth of capillary blood vessels to the affected area.<sup>138</sup> He tested various drugs for anti-angiogenic properties by an established, if somewhat crude, assay involving chick embryos (the “CAM” assay).<sup>139</sup> Among the drugs tested in February 1993 was taxol, a recently discovered anti-proliferative which was much in the news as a possible cancer treatment.<sup>140</sup> On the CAM assay, taxol was an extraordinarily effective inhibitor of angiogenesis, “even in minute concentrations.”<sup>141</sup>

Angiotech immediately filed for a patent.<sup>142</sup> The relevant claim was for a stent coated with taxol for treating a “narrowing of

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<sup>134</sup> See *Angiotech*, [2009] R.P.C. at 721.

<sup>135</sup> See *id.*

<sup>136</sup> See *id.*

<sup>137</sup> *Id.* (quoting Jean-Paul R. Herrman et al., *Pharmacological Approaches to the Prevention of Restenosis Following Angioplasty: The Search for the Holy Grail? (Part II)*, 46 *DRUGS* 249 (1993)).

<sup>138</sup> *Id.*

<sup>139</sup> *Id.*

<sup>140</sup> *Id.* at 722.

<sup>141</sup> *Id.*

<sup>142</sup> See *id.*

a body passageway” and for “treating or preventing restenosis.”<sup>143</sup> The application offered no proof that such a stent would work.<sup>144</sup> In fact, all Angiotech had done was to decide to investigate anti-angiogenesis as a possible way of dealing with restenosis, identifying taxol as a promising anti-angiogenic.<sup>145</sup>

In 2005 Conor Medsystems applied to revoke the patent on the grounds of obviousness.<sup>146</sup> Conor argued that, because Angiotech’s patent taught no more than that a taxol eluting stent was worth a try in the battle against restenosis, all Conor had to show was that it was obvious to try a taxol-coated stent.<sup>147</sup> This, Conor said, was obvious because it was obvious to try anti-proliferatives and taxol was an anti-proliferative much in vogue.<sup>148</sup> Angiotech countered that Conor’s approach was wrong in principle. What Conor had to show, it argued, was that it was obvious to use a taxol-coated stent to *treat* restenosis.<sup>149</sup> This, said Angiotech, was not obvious because there was no reason to think that taxol, out of all the other anti-proliferatives that might have been chosen, would actually work.<sup>150</sup>

The Patents Court and the Court of Appeal sided with Conor and held the patent invalid for obviousness.<sup>151</sup> In the Netherlands, however, the same obviousness attack had failed.<sup>152</sup> By the time the matter came before the House of Lords, Angiotech and Conor had settled their dispute.<sup>153</sup> The House of Lords took the case in an evident desire to resolve the tension between the results in the UK and Holland.<sup>154</sup> Having settled, Conor did not argue the case in the

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<sup>143</sup> *Id.*

<sup>144</sup> *Id.* at 723.

<sup>145</sup> *See id.* at 722.

<sup>146</sup> *Id.*

<sup>147</sup> *Id.* at 723 (quoting statement of Simon Thorley, Q.C.).

<sup>148</sup> *Id.*

<sup>149</sup> *See id.* (“That seemed a fairly straightforward issue and Angiotech no doubt prepared for trial clutching the Holy Grail paper as the best possible evidence that there was at the time no obvious solution to restenosis.”).

<sup>150</sup> *See id.*

<sup>151</sup> *Id.* at 720.

<sup>152</sup> *Id.*

<sup>153</sup> *Id.*

<sup>154</sup> *See id.*

House of Lords; Angiotech's opponent was the Comptroller of Patents.<sup>155</sup>

The Comptroller's case was based on a line of EPO authority in which the EPO had interpreted the EPC as enabling it to reject entirely speculative claims on the basis that they involved no inventive step.<sup>156</sup> The EPO took the view that, because the patentee had not actually solved an objective technical problem, the inventive step question simply did not arise.<sup>157</sup> It addressed the point at which a claim would become purely speculative in *Johns Hopkins University School of Medicine Case/Growth Differentiation factor-9*:

The definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting forward one, requires that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve.<sup>158</sup>

Lord Hoffmann took this "plausibility" requirement as the guiding principle in the *Angiotech* case:

These cases are in my opinion far from the facts of this case. The specification did claim that a taxol coated stent would prevent restenosis and Conor did not suggest that this claim was not plausible. That would have been inconsistent with the evidence of its experts that taxol was just the thing to try. It is therefore not surprising that implausibility was neither pleaded nor argued. The same was true of the proceedings in the Netherlands. . . . [T]here is in my opinion no reason as a matter of principle why, if a specification passes the threshold test of

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<sup>155</sup> *Id.*

<sup>156</sup> *Id.* at 727 ("There is also a line of authority in the EPO in which claims to broad classes of chemical compounds alleged to have some common technical effect have been rejected under [article] 56 (obviousness) when there was nothing to show they would all have that technical effect.").

<sup>157</sup> *See id.* at 727–28.

<sup>158</sup> Case T-1329/04, *Factor-9/Johns Hopkins*, ¶ 11, available at <http://www.epo.org/law-practice/case-law-appeals/pdf/t041329eu1.pdf>.

disclosing enough to make the invention plausible, the question of obviousness should be subject to a different test according to the amount of evidence which the patentee presents to justify a conclusion that his patent will work.<sup>159</sup>

Accordingly, like the Dutch, the House of Lords held the patent valid.<sup>160</sup> The formal dispute had centered on whether the inventive step question was to be considered by reference to the material claimed, or to some combination of the claims and the description.<sup>161</sup> Underlying this formal question was the same fundamental issue: had Angiotech actually given enough to justify its claimed monopoly? The experienced judges of the Patents Court and the Court of Appeal did not consider the CAM assay results enough.<sup>162</sup> The Dutch disagreed.<sup>163</sup> Rightly or wrongly, the House of Lords sided with the Dutch, citing the EPO's "plausibility" test as the relevant threshold.<sup>164</sup> It held that the CAM assay results were enough to make the invention "plausible," and that this was enough to justify Angiotech's monopoly.<sup>165</sup>

It was far from clear that the Dutch and the EPO had got it right. In *Johns Hopkins*, the EPO was surely correct to say that a claim will be obvious if the specification does not even make it plausible that the claimed invention actually works. But, all other things being equal, is the converse necessarily true? The lower courts took the view that the question of obviousness was, like claims breadth sufficiency, ultimately to be decided by reference to an inventor's contribution to the art—to substance rather than form.<sup>166</sup> In the interest of maintaining consistency with both another major European nation and the EPO, the House of Lords decided that form took precedence so long as the invention was merely "plausible." This was a major victory for patentees. But

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<sup>159</sup> *Angiotech*, [2009] R.P.C. at 728.

<sup>160</sup> *See id.* at 726.

<sup>161</sup> *See id.* at 723.

<sup>162</sup> *See id.* at 729.

<sup>163</sup> *Id.*

<sup>164</sup> *See id.* at 728.

<sup>165</sup> *See id.* at 729–30.

<sup>166</sup> *Id.* at 732 (Lord Walker of Gestingthorpe, concurring).

given the assessment that the case would have gone the other way in the absence of a desire to be *seen* to be following EPO case law, the decision served as the clearest indicator to date of the deference that the House of Lords was now paying to EPO case law.

VI. 2009—*GENERICS (UK) LTD. v. LUNDBECK*<sup>167</sup>

*Lundbeck* returned to the question posed in *Biogen*: whether the patentee had invented a “principle of general application” so as to justify a broad claim. The outcome was both surprising and controversial.

In 1989, citalopram entered the market for antidepressants.<sup>168</sup> It had been discovered and patented by Lundbeck.<sup>169</sup> The process for synthesising citalopram produced a racemate, i.e., an undifferentiated mixture of two alternative three-dimensional forms or “enantiomers” of the same molecule.<sup>170</sup> Nobody knew how to “resolve” the racemate, i.e., how to produce each of the enantiomers in its pure form,<sup>171</sup> and nobody knew whether citalopram’s pharmacological effect was attributable to one or the other of the enantiomers or to both.<sup>172</sup>

In 1987, Lundbeck succeeded in resolving the racemate.<sup>173</sup> It discovered that the anti-depressant effect was caused entirely by the (+)-enantiomer, escitalopram.<sup>174</sup> Lundbeck filed a patent for escitalopram.<sup>175</sup> Claim 1 of the patent was to escitalopram defined by its chemical formula.<sup>176</sup> Claim 6 of the patent was to Lundbeck’s method of producing escitalopram.<sup>177</sup>

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<sup>167</sup> *Generics (UK) Ltd. v. H Lundbeck A/S*, [2009] UKHL 12, [2009] R.P.C. 13.

<sup>168</sup> [2009] R.P.C. at 428 [59].

<sup>169</sup> *Id.*

<sup>170</sup> *Id.* at 414 [2].

<sup>171</sup> *Id.* at 428–29 [61].

<sup>172</sup> *Id.*

<sup>173</sup> *Id.* at 429 [62].

<sup>174</sup> *Id.*

<sup>175</sup> *Id.*

<sup>176</sup> *Id.* at 414 [5].

<sup>177</sup> *Id.*

In 2005, Generics applied to revoke the escitalopram patent.<sup>178</sup> It argued that all Lundbeck had done was to repatent the active ingredient in citalopram; that the way Lundbeck had succeeded in resolving the racemate was obvious; and that Lundbeck's real contribution to the art was to find *one* way of resolving the racemate, yet it sought to claim escitalopram made by *any* method per *Biogen* and *Kirin-Amgen*.<sup>179</sup>

The judge at first instance rejected the novelty and obviousness attacks, but accepted that the patent was insufficient by virtue of claims that were too broad.<sup>180</sup> That left Lundbeck with only a claim to its specific method of producing escitalopram. Lundbeck appealed. Exceptionally, Lord Hoffmann descended from the House of Lords to sit in the Court of Appeal, giving him the opportunity to revisit and explain the principle he had laid down in *Biogen*.<sup>181</sup>

First, Lord Hoffmann rejected the novelty attack on the strength of EPO case law on the disclosure (or, rather, non-disclosure) of enantiomers by racemates,<sup>182</sup> and the obviousness attack on the facts.<sup>183</sup> On sufficiency, he said this:

S.60(1) of the Act makes it clear that a claim may be either to a product or a process. In the case of a product claim, performing the invention for the purposes of s.72(1)(c) means making or otherwise obtaining the product. In the case of a process claim, it means working the process. A product claim is therefore sufficiently enabled if the specification discloses how to make it. There is nothing to say that it must disclose more than one way. The judge founded his decision entirely upon the decision of the House of Lords in *Biogen Inc v. Medeva plc* [1997] R.P.C. 1, which he subjected to a careful and detailed analysis. I shall try, with

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<sup>178</sup> *Id.* at 429 [65].

<sup>179</sup> *See* *Generics (UK) Ltd. v. Lundbeck*, [2007] R.P.C. 32, 737 [4].

<sup>180</sup> *See id.* at 795 [266].

<sup>181</sup> *See* *Lundbeck v. Generics (UK) Ltd.*, [2008] R.P.C. 19.

<sup>182</sup> *Id.* at 443 [9].

<sup>183</sup> *Id.* at 446 [25].

suitable diffidence to explain why I do not think that case yields so broad a principle.<sup>184</sup>

Lord Hoffmann explained that *Biogen* was decided as it was because it involved not a product claim, but a “product-by-process” claim.<sup>185</sup> By defining the product by the way in which it had been made, namely by recombinant DNA technology, the claim had inherently claimed a *class* of products, because the word “recombinant” encompassed a class of processes.<sup>186</sup> Pure product claims, he said, were different:

[The judge] treated the relevant “technical contribution to the art” as being the inventive step, namely a way of making the enantiomer. That, I respectfully consider, was a mistake. When a product claim satisfies the requirements of s.1 of the 1977 Act, the technical contribution to the art is the *product* and not the process by which it was made, even if that process was the only inventive step.

That proposition is in my opinion established by a number of decisions in the European Patent Office. In T0595/90 *Kawasaki Steel Corporation* [1994] O.J. E.P.O. 695 claim 1 was to a product, namely a certain description of high grade steel sheeting. In opposition proceedings, the Board of Appeal found that the claimed product “only has properties which were fully predicted and envisaged, i.e. the matter is obvious as such.” However, the Board went on, “this desideratum was not yet actually achieved” and was “hardly realisable on a commercial scale.” If the patentee had found a non-obvious way of making the product, he was entitled to a product

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<sup>184</sup> *Id.* at 447 [30–31] (citation omitted).

<sup>185</sup> *See id.* at 447 [33]. Lord Hoffman had disapproved of such claims in *Kirin-Amgen. See Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd.*, [2004] UKHL 46, [2005] R.P.C. 9, 198 [90] (H.L.).

<sup>186</sup> *See Lundbeck*, [2008] R.P.C. 19 at 448 [34].

claim, with the full monopoly of the product which that conferred.<sup>187</sup>

He went on to describe a number of other EPO authorities to the same effect and concluded:

*Biogen* should therefore not be read as casting any doubt upon the proposition that an inventor who finds a way to make a new product is entitled to make a product claim, even if its properties could have been fully specified in advance and the desirability of making it was obvious.<sup>188</sup>

Lundbeck's product claim was therefore valid.<sup>189</sup> Lord Hoffmann's judgment was upheld on the further appeal to the House of Lords.<sup>190</sup>

It is far from clear that the EPO got it right in *Kawasaki Steel* and the other product claim cases. As Lord Hoffmann observed, it had not even occurred to anyone that sufficiency should even be argued in these cases.<sup>191</sup> But this does not necessarily mean that it would not have been a good point, as it was in *Biogen*. The tension between the result in the two cases is obvious. Lord Hoffmann himself recognised as much.<sup>192</sup> He suggested that, ultimately, *Biogen* had been unfortunate because it could not make a pure product claim.<sup>193</sup> A DNA molecule which expressed HBV antigens was known to exist in nature, had been isolated in the form of the HBV genome and was therefore old.<sup>194</sup> This reasoning is unconvincing. What Professor Murray had made was clearly not the same as the HBV genome. Assuming, then, that Biogen could have found a way to describe Professor Murray's DNA molecule that did not use the word "recombinant," it appears to follow that Biogen would have been entitled to their broad monopoly after all.

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<sup>187</sup> *Id.* at 448 [36–37].

<sup>188</sup> *Id.* at 449 [40].

<sup>189</sup> *Id.* at 450 [47].

<sup>190</sup> *See* Generics (UK) Ltd. v. Lundbeck, [2009] UKHL 12, [2009] R.P.C. 13.

<sup>191</sup> *See* [2009] R.P.C. at 446–50 [26–47].

<sup>192</sup> *See id.* at 449 [42].

<sup>193</sup> *See id.*

<sup>194</sup> *See Biogen*, [1997] R.P.C. at 26.



Yet its actual contribution to the art would have remained the same.

Like *Angiotech*, then, *Lundbeck* was a triumph of form over substance designed to ensure consistency with the EPO. “Great persuasive authority” meant exactly what it said.

#### VII. 2011—*HUMAN GENOME SCIENCES V. ELI LILLY*<sup>195</sup>

In *Human Genome Sciences v. Eli Lilly* the issue was very similar to the issue in *Angiotech* save that the attack was industrial applicability rather than obviousness.

In 1996, Human Genome Sciences discovered a DNA sequence which coded for a member of the “TNF ligand superfamily” of proteins.<sup>196</sup> TNF ligands are proteins which act as intercellular mediators in inflammation and other immune responses.<sup>197</sup> HGS called its new member of the family “neutrokin- $\alpha$ .”<sup>198</sup> It had discovered neutrokin- $\alpha$  not by any laboratory technique, but by mining publicly available databases of human DNA sequence information using information technology techniques called “bioinformatics.”<sup>199</sup>

HGS applied to patent neutrokin- $\alpha$ .<sup>200</sup> The description essentially disclosed the sequence and structure of neutrokin- $\alpha$ , its tissue distribution and a prediction of its properties based on the general properties of the TNF ligand superfamily.<sup>201</sup> However, none of this was backed up with any specific information about neutrokin- $\alpha$  derived from any *in vivo* or *in vitro* experiments.<sup>202</sup> It

<sup>195</sup> *Human Genome Sciences, Inc. v. Eli Lilly & Co.*, [2011] UKSC 51, [2012] R.P.C. 6.

<sup>196</sup> *Id.*, [2012] R.P.C. at 109 [3]. The reader will recall that TNF itself was the subject of the applications in the *Asahi* case. *See Asahi Kasei Kogyo KK's Application*, [1991] R.P.C. 485 (H.L.).

<sup>197</sup> *Eli Lilly*, [2012] R.P.C. at 110 [7].

<sup>198</sup> *Id.* at 109 [3].

<sup>199</sup> *Id.* at 112 [17].

<sup>200</sup> *Id.* at 109 [4].

<sup>201</sup> *Id.* at 110 [7–8].

<sup>202</sup> *Id.*

couldn't be—the experiments had not yet been done and the specific information was not yet available.<sup>203</sup>

Eli Lilly applied to revoke the patent, arguing that HGS's "invention" was so speculative it was not capable of industrial application.<sup>204</sup> Lilly was successful before the examiners at the EPO and at first instance in the UK.<sup>205</sup> However, by the time the case came before the Court of Appeal in the UK, HGS had successfully appealed to the Technical Board of Appeal of the EPO.<sup>206</sup> In summary, the Board held that the skilled person would have appreciated "in the light of common general knowledge of the TNF ligand superfamily and its properties" that neutrokin- $\alpha$  would be active in directing the proliferation, differentiation and migration of T-cells and that this was enough to justify a monopoly.<sup>207</sup>

The Court of Appeal disagreed, holding that it need not give deference to the TBA on what it considered findings of fact and that the judge had been correct in law and fact.<sup>208</sup> It was an overt rejection of an EPO decision. In 2011, the matter came on before the newly formed Supreme Court.<sup>209</sup> Giving the leading judgment, Lord Neuberger observed:

In a number of recent decisions of the House of Lords, attention has been drawn to "the importance of UK patent law aligning itself, so far as possible, with the jurisprudence of the EPO (and especially decisions of its Enlarged Boards of Appeal)", to quote Lord Walker in *Generics (UK) Ltd v. H Lundbeck A/S*, [2009] R.P.C. 13, para.35. It is encouraging that the same approach is being adopted in Germany by the Bundesgerichtshof—see

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<sup>203</sup> *Id.*

<sup>204</sup> *Id.* at 114 [29].

<sup>205</sup> *Id.*

<sup>206</sup> *Id.* at 114 [30].

<sup>207</sup> *Id.*

<sup>208</sup> *Id.* at 115 [32].

<sup>209</sup> The House of Lords ended its judicial function on 30 July 2009; the Supreme Court opened on 1 October 2009.

Case Xa ZR 130/07 (10 September 2009), para. 33.<sup>210</sup>

He went on to point out that, while it was permissible for national courts to differ from each other and the EPO where the evidence in the various proceedings was different, and that there was “room for dialogue” between the national courts and the EPO, where the EPO had adopted a consistent approach to an issue in a number of decisions, the national courts should follow that approach.<sup>211</sup> This, he held, was the position with the EPO’s approach to industrial applicability.<sup>212</sup>

In view of the differing results between the result in the EPO on the one hand, and the result at first instance and in the Court of Appeal on the other, it was perhaps inevitable that the Supreme Court would hold that the courts below had failed properly to apply the principles developed by the EPO.<sup>213</sup> Lord Neuberger interpreted the EPO jurisprudence as meaning that a “plausible” or “reasonably credible” claimed use for an invention, or an “educated guess,” would suffice to satisfy the requirement of industrial applicability.<sup>214</sup> He held that the judge and the Court of Appeal had erred in applying a more stringent test, and finally observed:

Just as it would be undesirable to let someone have a monopoly over a particular biological molecule too early, because it risks closing down competition, so it would be wrong to set the hurdle for patentability too high . . . . Quite where the line should be drawn in the light of commercial reality and the public interest can no doubt be a matter of different opinions and debate.<sup>215</sup>

As in *Angiotech*, the UK Patents Court and the Court of Appeal had decided that the validity of a patent had to be decided by

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<sup>210</sup> *Eli Lilly*, [2012] R.P.C. at 127 [84].

<sup>211</sup> *Id.* at 128 [87].

<sup>212</sup> *Id.* at 136–38 [129–40]. See generally EPC, *supra* note 4, art. 57.

<sup>213</sup> See *Eli Lilly*, [2012] R.P.C. at 138 [140].

<sup>214</sup> *Id.* at 132 [107].

<sup>215</sup> *Id.* at 136–37 [130].

reference to the patentee's contribution to the art.<sup>216</sup> The lower courts took the view that what HGS had contributed was simply not enough; there was nothing in the specification of genuine use to the public, merely a protein sequence and some speculation on what it *might* do based on publicly available knowledge.<sup>217</sup> Again they were overruled by the highest appellate court in the interests of consistency with the EPO, which decided that the disclosure from HGS, which had satisfied the EPO, was good enough here too.<sup>218</sup> This was a case, like *Angiotech* and *Lundbeck* before it, where the House of Lords had clear scope to differ from the EPO but declined that opportunity. The status of the EPO as de facto final arbiter of the UK's law of patents was now firmly entrenched.

#### VIII. THE RISKS OF ALIGNMENT WITH THE EPO

As the above review demonstrates, the House of Lords has followed the EPO in every significant case since 1991 not because the Lords necessarily agreed but because, faced with a choice, they placed consistency above all else. Was this an abdication of the court's responsibility to interpret the law as they saw it?

Early on (in *Asahi*, *Merrell Dow*, *Biogen*, and *Kirin Amgen*) the answer to this question is probably not. In these cases there was every reason to agree with the EPO. Later on (in *Lundbeck*, *Angiotech*, and *HGS*) there was good reason to think the EPO had got it wrong. In *HGS* it was argued with some force that, being an office rather than a court, the EPO's case law had developed primarily in ex parte cases, and was too generous to patentees. The House of Lords rejected this argument, and accepted a decisive shift of the balance in favour of the patentee without challenge in the interests of maintaining uniformity. In principle, the House of Lords (and now the Supreme Court) made judgments only on questions of law, and its course has aligned UK law with the law as it is developed and applied by the EPO. In practice, however, the decisions of the EPO and the Courts are made in specific factual contexts and it is unrealistic to attempt to divorce

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<sup>216</sup> *Id.* at 103 [H7].

<sup>217</sup> *Id.* at 115 [31–34].

<sup>218</sup> *Id.* at 134–35 [120].

the legal question from its factual context. It is interesting to speculate whether, if the first instance judge had applied the legal test as eventually determined by the Supreme Court, he would also have made findings of fact that meant the outcome was no different. The legal tests leave room for judgment, as Lord Neuberger expressly recognized in his judgment in *HGS*. Adherence to the *law* determined by the EPO does not imply that courts reach the same determination. While EPO decisions have great persuasive authority on law, the same is not true in relation to findings of fact.<sup>219</sup> It is debatable whether the appellate system as operated in the UK, in which decisions are not remitted for further determination, guards sufficiently against the danger that following legal determinations will drag in factual findings by the back door.

#### IX. THE UNIFIED PATENT COURT

The steps to complete the European patent package are gathering pace. At the time of writing, the EU has put in place the two regulations underpinning the Unitary Patent.<sup>220</sup> The Agreement on a Unified Patent Court was signed on 19 February 2013<sup>221</sup> and the Rules of Procedure are in their fourteenth draft.<sup>222</sup>

<sup>219</sup> See, e.g., *Novartis AG v. Johnson & Johnson*, [2011] E.C.C. 10, 191 [62] (“[The TBA and other courts] did not have the benefit of the intensive probing of the facts and expert evidence afforded by cross-examination which is provided by English procedure. Sometimes that procedure is wasteful, but not in this case.”). A parallel can perhaps be drawn with the decisions of the CJEU which constitutionally is not able to make findings of fact. See *Arsenal Football Club Plc v. Reed* (No. 2), [2003] 1 C.M.L.R. 13, 388 [9], 393 [27], *rev’d*, [2003] 2 C.M.L.R. 25, 810 [25] (upholding the lower court on these points).

<sup>220</sup> Council Regulation 1257/2012, Implementing Enhanced Cooperation in the Area of the Creation of Unitary Patent Protection, 2012 O.J. (L 361); Council Regulation 1260/2012, 2012 O.J. (L 361) (for the latter, with regard to the applicable translation arrangements).

<sup>221</sup> Bulgaria is expected to sign once internal procedures are completed. Spain and Poland did not sign but the agreement remains open for signature. See Press Release, Council of the European Union, Signing of the Unified Patent Court Agreement (Feb. 19, 2013), available at [http://www.consilium.europa.eu/uedocs/cms\\_Data/docs/pressdata/en/intm/135593.pdf](http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/en/intm/135593.pdf).

<sup>222</sup> At the time of writing, the Preliminary set of provisions for the Rules of Procedure of the Unified Patent Court, fourteenth draft, is available at [http://www.upc.documents.eu.com/PDFs/2013-01-31\\_Rules\\_of\\_Procedure\\_Draft\\_14\\_\(15829021\\_1\).pdf](http://www.upc.documents.eu.com/PDFs/2013-01-31_Rules_of_Procedure_Draft_14_(15829021_1).pdf).

There is still much to be done: the Agreement must be ratified by thirteen Member States, the Rules finalised, fee levels set, judges appointed and trained, local and regional divisions established, and budgets, buildings and IT systems put in place. Consequential changes are needed in the European Patent Convention, the “Brussels” Regulation 44/2001 on civil jurisdiction and the SPC Regulations 469/2009 and 1610/96. There is no doubt that that is a substantial list, but there appears to be the political will to see it through.

Under a Unified Patent Court, the relationship between the Unified Court and the EPO may become analogous to the relationship between a national courts and its national office. The Court will have power under the Rules to supervise the administrative tasks of the EPO in relation to unitary patents.<sup>223</sup> Over time the Unified Court may also come to regard itself as the senior forum for determining substantive questions of law and validity. It might be argued that, in view of the recent history at least in the UK, this is a welcome development. How long it takes the new Court to develop the confidence to review and depart from existing case law of the EPO remains to be seen.

A great deal of debate in the legislative history of the Unified Patents Court focussed on the role of the Court of Justice of the European Union. Practitioners were greatly concerned at the effects on substantive patent law of the delays and inexperience in patent matters that that would incur. Concern focussed in particular of Articles 6–8 of the draft for Regulation 1257/2012, and was largely assuaged when those Articles were replaced, following a compromise meeting of legislators on 19 November 2012.<sup>224</sup>

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<sup>223</sup> See *id.*, Rules 85–96.

<sup>224</sup> See UK Parliament House of Commons European Scrutiny Committee, 3 *European Unitary Patent*, available at <http://www.publications.parliament.uk/pa/cm201213/cmselect/cmeuleg/86-xxi/86xxi06.htm> (last visited Feb. 22, 2012); European Parliament Legislative Resolution of 11 December 2012 on the Proposal for a Regulation of the European Parliament and of the Council Implementing Enhanced Cooperation in the Area of the Creation of Unitary Patent Protection, COM (2011) 0215 (Dec. 11, 2012), available at <http://register.consilium.europa.eu/pdf/en/12/st16/st16304.en12.pdf>.

Just as the EPO is open to accusations that, as a patent awarding office, it develops the law in a direction that is unduly friendly to patentees, one can anticipate that legal developments in the new courts will be examined for policy influence. From the Unified Patent Court, staffed with specialist patents judges, it would be difficult to anticipate any particular policy direction beyond the efficient operation of justice over the patents system. The same would not have held true had the policy influence been directed from the Court of Justice of the European Union. This is a first important step towards establishing the credibility of the new court.

It remains unclear when the effects of the new patent package will really be felt. It is up to patentees<sup>225</sup> to choose whether they want a patent with unitary effect or to continue with the present system. It is also up to patentees to choose whether to opt their patents out of the system—an opt-out will be open for seven years after the Agreement enters into force.<sup>226</sup> Thus, even when the system is up and running, it can only be expected to succeed if patentees believe it will be an improvement over the existing system.

It is difficult to overestimate the cynicism and even hostility that greeted the proposals for the system, in the UK and elsewhere. In one particularly scathing examination of the position, published in May 2012, the UK parliament's cross-party European Scrutiny Committee concluded:

Although the theory of a unitary patent and unitary patent court in Europe has long been thought desirable, the practice has long been elusive. The latest attempt appears, regrettably, to be a further example of this. Moreover, some of the criticisms raised by witnesses result from traits that are so ingrained in the operation of the EU that a legitimate question arises whether an effective

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<sup>225</sup> Council Regulation 1257/2012, recital 5.

<sup>226</sup> Council Agreement on a Unified Patent Court 16351/12, art. 83, *available at* <http://register.consilium.europa.eu/pdf/en/12/st16/st16351.en12.pdf> (last visited Feb. 22, 2013).

unitary patent can ever be achieved within the confines of the EU's internal legal order.

We conclude overall that the draft agreement on the Unified Patent Court is likely to hinder, rather than help, the enforcement of patents within the European Union. This will particularly be so for SMEs, the main intended beneficiaries. Given our concerns, it is vital that the UK Government adopts a strong position reflecting the concerns of practitioners in final negotiations, as well as calling for the Central Division to be in London in order to mitigate the most damaging effects of a unitary EU-wide patent.<sup>227</sup>

Now the proposals are reaching the point of reality, that cynicism has been tempered on two accounts: by changes to the proposals and by a coming to terms with a reality. This can be seen in the paper produced from the European Scrutiny Committee when it considered the position anew in February 2013. While much of their concern has abated, they still conclude that questions remained to be resolved:

8.27 We note the changes to the UPC Agreement since we published our Report, *The Unified Patent Court: Help or Hindrance?*, on 3 May last year. The most significant change is the removal of the ECJ's jurisdiction over the infringement of unitary patents, which was a principal recommendation of our Report.<sup>228</sup> We are also pleased to note that at least part of the Central Division will be located in London; that there is scope for extending the transitional provisions by a further seven years; and that Supplementary Protection Certificates will fall within the UPC's jurisdiction.

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<sup>227</sup> HOUSE OF COMMONS EUROPEAN SCRUTINY COMMITTEE, *THE UNIFIED PATENT COURT: HELP OR HINDRANCE?*, 2010–12, H.C. 1799-I, ¶ 186–87 (U.K.).

<sup>228</sup> See *supra* note 224 and accompanying text.



8.28 However, many of the concerns with the UPC still remain, in particular the effect of bifurcation on forum shopping, the training and quality of UPC judges, the prohibitive expense of using the unitary patent and UPC, particularly for SMEs, and the lack of an up-to-date Commission impact assessment (we remain doubtful at this stage of the benefits to business suggested by the Minister in paragraph 8.24 above).

8.29 Given that the negotiations on the UPC Agreement have now concluded, we are content to clear it from scrutiny. The Minister says, however, that:

*“Further negotiations among the signatories will also be necessary to finalise the rules of procedure for the court, to set the level of patent and court fees and establish the governance mechanisms for the court. The Government will ensure that it continues to influence the operational details related to the Agreement and that the views of UK stakeholders are considered in the wider discussions. Separately, signatories will need to consider whether to establish local or regional divisions of the court.”*[44]

8.30 In the light of this, we would be grateful if the Minister would write to us at the conclusion of the negotiations on the rules of procedure summarising their content and explain to what extent they mitigate the outstanding concerns we list above, and to what extent they reflect the views of the stakeholders which the Government will be consulting.<sup>229</sup>

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<sup>229</sup> See UK Parliament House of Commons European Scrutiny Committee, 8 *European Unitary Patent*, available at <http://www.publications.parliament.uk/pa/cm201213/cmselect/cmeuleg/86-xxx/8610.htm> (last visited Feb. 22, 2013).

CHANGING PRACTICE—THE LAST TWENTY YEARS, AND THE  
COMING DECADE

Looking back over the last twenty years, the development in the law, and in particular the significance of the EPO, has been paralleled by the internationalization of the role of the practitioner.

In the early 1990s, practice in the UK was emerging from a period of introspection. We had been working over a decade or so to address recognised deficiencies in a system that was thought to be slow, expensive and overly rigid. By the early 1990s, our patents courts had been through an overhaul. They brought cases rapidly to trial, with experienced and respected judges, backed by a broad and able profession in London. We had discovery confined to reasonable proportions, and a flexible court procedure under the parties' control that gave real scrutiny to the issues, including those under cross-examination. When we were preparing for trial, we were focused on prior art, on discovery, on expert reports, and on experiments, and then in trial we dealt with the issues through cross-examining witnesses. That underpinning remains largely in place to this day, and arguably provided a blueprint that heavily influenced the broader overhaul of the UK civil justice system. The UK system has not been heavily influenced by the developments in e-discovery that have shaped procedural developments in the United States, principally because discovery in the UK has been so confined. It is no longer a trawl, but a much more targeted and narrower exercise. Email, social media, the incursion of private and social communications, and bring-your-own-device into the workplace create new challenges for discovery. However, the extent to which discovery has been confined in UK patents cases makes it likely that patent litigation will be following developments in discovery-heavy actions in other parts of civil justice rather than seeking to lead developments.

Back in the early 1990s, UK practitioners were already in dialogue with our judges. This feature of the system has grown and matured over the time. Currently two judges (Floyd and Arnold JJ) hear most of the High Court cases at first instance with one further judge (HHJ Birss) hearing cases in the Patents County Court. Appellate cases are mostly heard in a panel that includes Kitchen LJ, the former senior patents judge, and before that Jacob

LJ took the same role. Lord Neuberger, well known for his interest in patents cases, has taken over a leading role from Lord Hoffmann in Supreme Court patent cases. The cadre of judges hearing most of the cases is therefore small. They are without exception well known to and well liked by the profession, which recognizes that they have all gone a long way to make themselves available and to listen to the views of practitioners on the development of practice and on points of concern. This is not a new phenomenon. It was the result of a movement given impetus by Mr. Justice Jacob when he was first appointed and enthusiastically pursued by his successors. The role of the late Sir Hugh Laddie and Sir Nicholas Pumfrey in furthering the approachability of our judges should not be overlooked or underestimated. As a result, over the last twenty years it has increasingly been the case that practice develops through a genuine dialogue between practitioners and the small group of judges before whom we practice most often.

Twenty years ago, practitioners were beginning to take an interest in the law in other parts of Europe. There were potential tools in other jurisdictions that could be useful in particular circumstances—the *saisie contrafaçon* in France (and Belgium) being a prime example. Over the 1990s, we watched the development of torpedoes in Italy (and Belgium) but, it is fair to say, there was considerable doubt as to the wisdom of using those tactics in the context of a UK action. It was well known that the UK judges may assume that a party that was trying to keep a case out of court had something to hide; that assumption would be given strength by such nefarious and transparent tactics as the torpedo actions. There are enough implements in the UK judicial toolbox to address most matters of which the courts take a dim view and, consequently, this jurisdictional contrivance was not widely relied upon in UK cases. In general, while torpedoes were in their heyday, UK professionals would advise clients on why what looked like a great tactic in theory was in fact not such a good idea in practice. Thankfully, the tactic was rarely used. When

torpedo actions came to an end with *Roche v. Primus*<sup>230</sup> and *GAT v. LuK*,<sup>231</sup> few mourned their passing.

While procedural games like the torpedo have not played a huge part of UK practice, the same cannot be said about substantive judgments. Most large patent cases that fight in the UK are also being fought in at least The Netherlands, Germany and perhaps France, Italy, the United States and elsewhere as well. Twenty years back, co-ordination of these actions was primarily (a) a matter of cost-saving by not duplicating work that had already been done and (b) a way to avoid the difficulties that arise from a witness being cross-examined against a backdrop of different testimony before various courts. UK first instance judges used to pay little interest to findings in parallel litigation in other jurisdictions. One judge is famously rumoured to have opened the folder “judgments of other jurisdictions” only after he had written his judgment, and even then only to check that the overseas court had come to the right decision. Mandated by the House of Lords to defer to EPO decisions, and with the UK judges seeing more and more of their European brethren at judges’ conferences and elsewhere, the island mentality gradually eroded. Practitioners started to read judgments from courts around Europe, to debate comparative law, to use those cases in court as persuasive authorities, and through this to promote the broader European patent order.

While UK courts may initially have been reluctant to pay much regard to foreign judgments, if anything the opposite is now true. The clearest exposition of the position came in *Grimme v. Derek Scott*<sup>232</sup> where the Court of Appeal heard a case without being told by either party that the same case had been the subject of a Dutch judgment. Jacob LJ was unimpressed, saying:

Following oral argument we undertook some legal research of our own and the opportunity of asking judicial colleagues in Germany and Holland as to whether they had any case law on the equivalent

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<sup>230</sup> Case C-539/03, *Roche v. Primus*, 2006 E.C.R. I-6535.

<sup>231</sup> Case C-4/03, *GAT v. LuK*, 2006 E.C.R. I-6509.

<sup>232</sup> *Grimme Landmaschinenfabrik GmbH & Co. KG v. Scott*, [2011] F.S.R. 7.

provisions to s. 60(2). Indeed they had (and an unreported case of Jacob J also emerged). The Dutch Judge told us that his court had even considered the case of a man selling Mr Scott's very machine. We were astonished that the parties, particularly Grimme who were the Dutch plaintiffs, did not tell us about that case.

Accordingly we sought further written argument on the point.

Advocates should recognise that where a point of patent law of general importance, such as the construction of a provision which by Treaty (either the EPC or the Community Patent Convention) is to be implemented by states parties to those conventions, has been decided by a court, particularly a higher court, of another member state, the decision matters here. For, despite the fact that there is no common ultimate patent court for Europe, it is of obvious importance to all the countries of the European Patent Union or the parties to the Community Patent Convention ("the CPC"), that as far as possible the same legal rules apply across all the countries where the provisions of the Conventions have been implemented. An important decision in one member state may well be of strong persuasive value in all the others, particularly where the judgment contains clear reasoning on the point.

Broadly we think the principle in our courts—and indeed that in the courts of other member states—should be to try to follow the reasoning of an important decision in another country. Only if the court of one state is convinced that the reasoning of a court in another member state is erroneous should it depart from a point that has been authoritatively decided there. Increasingly that has become the

practice in a number of countries, particularly in the important patent countries of France, Germany, Holland and England and Wales. Nowadays we refer to each other's decisions with a frequency which would have been hardly imaginable even twenty years ago. And we do try to be consistent where possible.

The Judges of the patent courts of the various countries of Europe have thereby been able to create some degree of uniformity even though the European Commission and the politicians continue to struggle on the long, long road which one day will give Europe a common patent court.<sup>233</sup>

It can seem at times that this direction—that the reasoning of a court in another member state is one the court should try to follow—leads to appellate courts giving more deference to the first instance (and even interlocutory) decisions of other member states than they give to the UK first instance decision under appeal. It also means that the basis of decisions is examined and re-examined, and the courts are increasingly alive to differentiated arguments. What it has meant for practitioners is an ever-increasing focus on the first decision in Europe, and thereafter on playing out the same arguments and decision for confirmation by a succession of other European courts. The consequence is that practice genuinely has moved on to a European level. It is no longer possible to run patent litigation in Europe wearing national blinders. Strategic decisions have to be taken with an eye on how it will be played out around Europe. Consistent argumentation is no longer a luxury but a necessity.<sup>234</sup>

The race for consistency has consequences in practice. The primary consequence has been an increasing pressure on timetables. The knowledge that the first judgment will be the guiding one could lead courts either towards speeding trials up so

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<sup>233</sup> *Id.* at 215 [77–81].

<sup>234</sup> *See, e.g.,* Novartis AG v. Johnson & Johnson Med. Ltd., [2011] E.C.C. 10, 190–91 [59–62].

as to be the primary decision maker for Europe, or slowing cases down so as to ease the process by having decisions to follow. The UK court in general appears to favour the former camp, and practice here over the last twenty years has been characterised by trying to fit broadly the same amount of work into increasingly tight timetables. That process has been assisted by the growth in instantaneous communications and working practices; in fact the only point of weakness in further acceleration appears to be the capacity of individuals to work beyond the first twenty-four hours of each day. At the same time, the last decade in particular has seen a growing recognition that legal practice has to become more diverse and accessible. The tensions are already growing between case timetables predicated on twenty-four-hour availability of all the lawyers involved on the one hand, and on the other new entrants to the profession with ambitions to combine practice with responsibilities and ambitions outside of their professional life.

The UK system has particular difficulties in this regard. The very flexible UK procedure means that many features of procedure can be the subject of judicial decisions and that in turn leads to many interim applications on short notice. As European influence grows, and particularly as the Unified Patents Court becomes a reality, one can anticipate that interim applications are going to become far less frequent and flexibility less available. While that may sound like a disadvantage, it could considerably reduce costs, encourage the planning that makes workloads more manageable for those with responsibilities outside of work, and avoid obstacles in bringing cases to trial on a planned pathway.

A second consequence of a race to consistency has been to question over-engineered aspects of the existing systems. The UK system is well equipped to handle large, complex cases but has for years been poorly adapted to the problems of small and medium sized enterprise ("SME"). The proposals go back at least as far as the Committee chaired by Sir Derek Oulton in 1987, which led to the establishment of the Patents County Court (PCC) in 1990. The court had a shaky start and by 1999 was hearing very few cases. It was re-launched in 2001 with the appointment of HH Judge Fysh QC but concerns remained that there was little difference in practice between Patents County Court and High Court procedures.

Proposals for reform were published in July 2009 and adopted in 2010, which also saw the appointment of a new judge, HHJ Birss QC. The PCC now limits evidence, discovery, trial time and cost recovery, and is proving attractive to the SME audience for which it was intended. And the result is perhaps more akin to practice elsewhere in Europe. Twenty years ago, the advice practitioners gave to SMEs about patent litigation tended to be not to bring it, or (if advising a defendant) to find a way to give up as quickly as possible. The Patents County Court has changed that. One can anticipate that PCC business will continue to grow for the foreseeable future. The change has great significance for the profession. If volumes of PCC work continue to grow then the normal practitioner workload may change from one or a handful of giant cases to a large number of small cases—more in line with practice elsewhere in Europe. As this is new work, it also could generate significant extra demand for litigation services, for which lawyers and patent attorneys are competing. Whether the resources are sufficient to meet demand only time will tell. The parallel operation of both a short and a full procedure in one jurisdiction helps identify the strengths and weaknesses of each and could, perhaps, provide useful information for the development of the practice and procedure of the Unified Patents Court—it is notable that the new court’s draft Rules set out, at the outset, that “complex cases may require more time and procedural steps and simple cases less time and less procedural steps.”<sup>235</sup>

Twenty years ago, practitioners in the UK had little information about other cases. While UK courts were in principle “open justice,” in practice interim applications were generally in private, and the only information publicly available was the writ. This has changed—a little. Judgments are now generally available online quickly (usually through the excellent bailii.org site). Almost every court hearing in patent cases is now open to the public. More documents are in principle available from the court file. But it is very far from perfect. Requests to the court office for copies of pleadings are slow, expensive, time consuming and

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<sup>235</sup> See Preliminary set of provisions for the Rules of procedure of the Unified Patent Court at 15 (Preamble), *available at* [http://www.upc.documents.eu.com/PDFs/2013-01-31\\_Rules\\_of\\_Procedure\\_Draft\\_14\\_\(15829021\\_1\).pdf](http://www.upc.documents.eu.com/PDFs/2013-01-31_Rules_of_Procedure_Draft_14_(15829021_1).pdf) (last visited Feb. 22, 2013).



not always successful. Many documents are only available after the considerable expense of an application and (brief) hearing. Truly open justice is still some distance away.

Looking across the channel, UK practitioners appreciate that even the modest openness achieved over the last twenty years places the UK far ahead of the rest of Europe. Without openness, it is difficult to make direct comparisons, hold parties to account for their statements to courts, and ensure courts are able to hear the full picture. But any smugness about the UK system is rapidly dispelled on examining the U.S. approach. PACER—while it is much derided in the United States—goes far beyond anything available in the UK. It helps inform the U.S. system about its own functionality and provides the ready means to hold witnesses and parties to account. It is notable that it provides a primary source of information for UK practitioners which our own systems cannot provide. There are no plans to replicate PACER in the UK and no realistic hope that over the next ten years we will see similar openness here or indeed in any part of Europe. This is a pity, because without the information that an open system breeds, one cannot see the needs for reform that undoubtedly exist and that would drive a better, more uniform and more functional European system. When the Unified Patents Court comes into being it will, from the outset, have on-line inspection facilities for pleadings, evidence, decisions and orders.<sup>236</sup> Perhaps that will encourage the UK to catch up.

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<sup>236</sup> See Preliminary set of provisions for the Rules of procedure of the Unified Patent Court at 109 (Rule 262), available at [http://www.upc.documents.eu.com/PDFs/2013-01-31\\_Rules\\_of\\_Procedure\\_Draft\\_14\\_\(15829021\\_1\).pdf](http://www.upc.documents.eu.com/PDFs/2013-01-31_Rules_of_Procedure_Draft_14_(15829021_1).pdf) (last visited Feb. 22, 2013).